



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PH-2014-PCT		FOR FURTHER ACTION See Form PCT/IPEA/416																
International application No. PCT/JP2004/005006	International filing date (day/month/year) 07.04.2004	Priority date (day/month/year) 10.04.2003																
International Patent Classification (IPC) or national classification and IPC																		
Applicant GHEN CORPORATION																		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of _____ sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0"><tr><td><input checked="" type="checkbox"/> Box No. I</td><td>Basis of the report</td></tr><tr><td><input type="checkbox"/> Box No. II</td><td>Priority</td></tr><tr><td><input type="checkbox"/> Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td><input type="checkbox"/> Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td><input checked="" type="checkbox"/> Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td></tr><tr><td><input checked="" type="checkbox"/> Box No. VI</td><td>Certain documents cited</td></tr><tr><td><input type="checkbox"/> Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td><input checked="" type="checkbox"/> Box No. VIII</td><td>Certain observations on the international application</td></tr></table>			<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand		Date of completion of this report																
Name and mailing address of the IPEA/JP		Authorized officer																
Facsimile No.		Telephone No.																

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/005006

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

- ☐ the claims:
- nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* _____ received by this Authority on _____

nos.* _____ received by this Authority on _____

- ☐ the drawings:
- sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims		YES
	Claims	1-8	NO
Inventive step (IS)	Claims		YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: KR 2003/26046 A (BIOLAB CO., LTD.), 31 March 2003, entire document (Family: none)

Document 2: JP 2001-525314 A (XIMED Group PLC.), 11 December 2001, entire document; claims 1, 26, 28 to 31; examples 1 to 10 & WO 99/2187 A1 & AU 9882326 B & EP 1001809 A1

Document 3: JP 2002-27979 A (The Nippon Synthetic Chemical Industry Co., Ltd.), 29 January 2002, entire document (Family: none)

Document 4: JP 8-12584 A (Yakult Honsha Co., Ltd.), 16 January 1996, entire document; paragraphs [0002] and [0040] (Family: none)

Document 5: JP 58-225026 A (Mochida Pharmaceutical Co., Ltd.), 27 December 1983, entire document; page 2, upper left column, lines 9 to 15 (Family: none)

Document 6: JP 2-121908 A (Kabushiki Kaisha Ghen Corp.), 9 May 1990, entire document (Family: none)

[1]

Document 1 indicates that a composition containing an antibody (IgY) ingredient originating from an egg laid by a hen immunized with sucrase and maltase is applied as

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

the active ingredient of an antiobestic agent based on the inhibiting action of the aforementioned sucrase and maltase.

Therefore the invention set forth in claims 1 to 8 lacks novelty and does not involve an inventive step in the light of document 1.

[2]

Document 2 indicates that a composition containing an antibody (IgY) ingredient originating from an egg laid by a hen immunized with lipase is applied as the active ingredient for an antiobestic agent based on the inhibiting action of lipase. In this way, a dietary enzyme inhibitor/antiobestic agent having as its active ingredient a composition containing an IgY ingredient originating from an egg laid by a hen immunized with a dietary enzyme was known at the time of filing of this application.

Document 2 does not indicate that two or more types of dietary enzyme are used as immunogens. However, improving obesity by applying a compound ingredient having inhibiting activity with respect to a dietary enzyme such as alpha-glucosidase, amylase, trypsin or lipase was a known technique at the time of filing of this application as described in documents 3 to 5, and when doing so the concept of inhibiting a plurality of types of dietary enzyme is disclosed in document 5. In addition, the method of preparing an IgY antibody-containing hen's egg ingredient having as an immunogen the same dietary enzyme as the enzyme described in documents 1 and 2 per se was a known technique at the time of filing of this application, as described not only

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

in documents 1 and 2 but also in document 6.

Therefore it would not be technically difficult for a person skilled in the art to prepare the IgY antibody ingredient obtained having a known dietary enzyme other than the dietary enzymes set forth in documents 1 and 2 as the immunogen, and to apply said ingredient together with the IgY antibody ingredient disclosed in either document 1 or 2, and it would be easy for a person skilled in the art to predict that doing so would more effectively hinder the digestive action and result in a more effective antiobestic than when either IgY ingredient is applied alone.

Therefore the invention set forth in claims 1 to 8 does not involve an inventive step in the light of documents 1 to 6.

The embodiments of drawings and the description of this application only indicate that better results are obtained when IgY ingredients for specific two types of dietary enzymes are prepared and combined than when each of the IgY ingredients is applied alone, and the fact that the aforementioned advantageous effect is synergistically advantageous beyond the additional antiobestic effect which may be expected if the IgY ingredients are used in isolation is not sufficiently explained to allow a specific and logical understanding. Moreover, it is unclear from the drawings and description of this application that an advantageous dietary enzyme inhibiting effect and/or antiobestic effect that goes beyond that expected from each of the documents (i.e. a symbiotic effect) is offered by all combinations of two or more types of dietary enzyme included in the

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

descriptions of the claims, or a combination of all IgY
antibody-containing ingredients.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
KR 2003/68728 A [E, Y]	25.08.2003	16.02.2002	
JP 2003-259884 A [E, Y]	16.09.2003	06.01.2003	07.01.2002
JP 2003-192695 A [E, Y]	09.07.2003	27.12.2001	

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

(1)

Among the compositions as specified in claims, specific data based on Examples cannot be proved concerning those containing components derived from an egg laid by a hen having been immunized by two or more "digestive enzymes or fragments thereof" for an individual, as specified in, for example, claim 2. Thus, they are neither fully supported by the description in the meaning within PCT Article 6 nor sufficiently disclosed in the description in the meaning within PCT Article 5.

(2)

Among the compositions as specified in claims, those wherein a digestive enzyme fragment is employed as an immunogen for a hen are neither fully supported by the description in the meaning within PCT Article 6 nor sufficiently disclosed in the description in the meaning within PCT Article 5.